

**THE HIGH COURT**

**COMMERCIAL**

**[2022] IEHC 234**

**[2021 No. 2527 P]**

**BETWEEN**

**NOVARTIS PHARMA AG**

**PLAINTIFF**

**AND**

**ELI LILLY NEDERLANDS B.V.**

**And**

**ELI LILLY KINSALE LIMITED**

**And by Order**

**ELI LILLY AND COMPANY (IRELAND) LIMITED**

**And**

**ELI LILLY AND COMPANY LIMITED**

**DEFENDANT**

**THE HIGH COURT**

**COMMERCIAL**

**2021/2/PAP**

**IN THE MATTER OF EUROPEAN PATENT (IE) 2 784 084 ENTITLED  
“ANTAGONIST ANTIBODIES TO IL-17A/F HETEROLOGOUS POLYPEPTIDES”  
FILED ON 2 JUNE 2004 AND REGISTERED IN THE NAME OF NOVARTIS  
PHARMA AG**

**-AND-**

**IN THE MATTER OF THE PATENTS ACT 1992 AND THE PATENTS  
(AMENDMENT) ACT 2006**

**JUDGMENT OF Mr. Justice Twomey delivered on the 26<sup>th</sup> day of April, 2022**

**BACKGROUND**

1. This is a dispute between two multinational pharma companies, the plaintiff, Novartis Pharma AG (“Novartis”) and the defendants (“Eli Lilly”), relating to European patent (IE) 2 784 084, entitled ‘Antagonist antibodies to IL-17A/F heterologous polypeptides’ (the “Patent” or the “084 Patent”) owned by Novartis. The Patent covers products directed towards antibodies that act as antagonists to a protein that is implicated in immunity related diseases like psoriasis.
2. The first set of proceedings is a revocation action (the “revocation action”) taken by Eli Lilly against Novartis on the 13<sup>th</sup> April, 2021 in relation to the Patent.
3. Eli Lilly’s application for the revocation of the Patent is brought in circumstances where it claims that the Patent is directed towards antibodies that act as *antagonists* to IL-17A/F but where the scope that Novartis asserts for the Patent extends to antibodies that *bind to* IL-17A/F and function to antagonise IL-17A/F *irrespective* of whether they bind to other proteins including the prior art related proteins, IL-17A/A or IL-17F/F. This is the basis upon which Novartis asserts the Patent over Eli Lilly’s own antibody ixekizumab, which is a therapy for

immunity-related illnesses supplied to patients, sold under the product name *Taltz*. Novartis' competing product is called *Cosentyx*.

4. Eli Lilly claims, *inter alia*, that the Patent currently owned by Novartis should not have been granted as it lacks novelty, it is obvious and lacks sufficiency.

5. The second set of proceedings are patent infringement proceedings (the "infringement action") taken by Novartis against Eli Lilly on the 15<sup>th</sup> April, 2021 in relation to Eli Lilly's product, *Taltz*, which Novartis alleges breaches Novartis' Patent.

6. Eli Lilly claims, as a defence to the infringement action, that the Patent is invalid, that *Taltz* does not come within the claims of the Patent, as properly construed and that Novartis' acquisition of the Patent, and its alleged use by Novartis to seek to prevent competition from Eli Lilly, constitutes an abuse of a dominant position in breach of competition law.

7. In this regard, Eli Lilly claims that Novartis has a dominant position in the market for products targeted at the treatment of psoriasis where a high degree of efficacy and speed is required. Eli Lilly relies on these same competition law issues to support its counterclaim in the infringement action. It also claims that the injunctive remedy, which is being sought by Novartis, would impose a disproportionate hardship to patients who rely on *Taltz*.

### **The Patent**

8. The Patent was originally held by a company called Genentech Inc. The Patent was filed by Genentech Inc. on 2<sup>nd</sup> June, 2004 and the priority date of the Patent is 8<sup>th</sup> July, 2003. Genentech Inc. did not develop any product on the basis of the Patent.

9. Novartis acquired the Patent after entering into an 'Asset Purchase, License, and Settlement Agreement' dated 23<sup>rd</sup> April, 2020 with Genentech Inc, which is some 17 years after the Patent was granted. The Patent was then assigned to Novartis by Genentech Inc. on 25<sup>th</sup> September, 2020.

**10.** Prior to Novartis' acquisition of the Patent from Genentech Inc., European Patent EP 1 641 822 (the "Patent '822") the parent patent of the Patent, was successfully challenged in Opposition proceedings before the European Patent Office ("EPO"). This was because prior to its acquisition of the Patent from Genentech Inc. Novartis objected to the EPO against the granting of the '822 Patent on the basis that the European patent was already being asserted against Eli Lilly's product *Taltz* in national proceedings beyond the scope of any valid monopoly that could be claimed for it. It is also the case that Novartis objected to the Patent on grounds of invalidity, prior to its acquisition of the Patent from Genentech Inc.

**11.** Novartis had also initiated challenges to the parent patent, the '822 Patent, in 2014 and 2019.

**12.** Eli Lilly claims that this factual background is relevant to the discovery process, as it claims these are an unusual set of facts and it points out that it spans a long period of time from the priority date of 8<sup>th</sup> July, 2003 to date.

**13.** It is against this background that discovery is sought by both parties against the other in both the revocation and the infringement actions. Hence there are four separate motions for discovery. First the two discovery motions in the revocation action will be addressed, followed by the two discovery motions in the infringement action.

**14.** What is unusual in these proceedings, compared say to other litigation, is that in some respects both parties are looking for similar types of documents from each other e.g. it is common case that Novartis' categories 3 and 6 which it seeks in the revocation action are very similar to Eli Lilly's Categories 1-6 which it seeks in the revocation action e.g. documents which either party has which relates to any antibody which binds to and inhibits IL-17A/F.

**15.** It is against this background that it is relevant to consider the manner in which the Irish courts have applied discovery principles to the very specialised and technical area that is patent litigation.

## **THE APPLICABLE LAW RELATING TO DISCOVERY**

16. There is no dispute between the parties regarding the principles of discovery which apply to this case, namely as recently restated by the Supreme Court in *Tobin v. Minister for Defence* [2020] 1 I.R. 211 and these do not need to be restated in this judgment.

### **Manner in which discovery principles are applied to patent litigation**

17. The leading case in relation to discovery in patent cases is *Boehringer Ingelheim Pharma GmbH v. Norton (Waterford) Ltd* [2016] IECA 67 and it seems clear to this Court that the subsequent restatement of the principles applicable to discovery in *Tobin* has not lessened the significance of *Boehringer* as a precedent in patent cases.

18. This is because, as noted at para. 12 of the judgment of Finlay Geoghegan J. in *Boehringer*, the principles applicable to discovery in patent cases is no different to the principles applicable to discovery in non-patent cases. It is simply that in applying these principles in patent litigation, account needs to be taken of the very specialised and technical area to which they are applied. Accordingly, it seems clear to this Court that there can be no question but that the principles applicable to discovery, which existed prior to *Tobin* and which were restated in *Tobin*, continue to apply to patent cases and non-patent cases.

19. *Boehringer* did however clarify how those principles apply to the very specialised and technical area that is patent disputes, where expert evidence (as distinct from the acts or opinions of the patentee or indeed the challenger) is crucial, particularly when a court is considering if documents in the possession of a patentee or a challenger are in fact ‘necessary’ to be discovered, even though they are relevant.

20. As noted by Finlay Geoghegan J. at para. 32 in the context of the claim of obviousness and inventiveness in that patent revocation case, the ‘*primary evidence at trial will be that of properly qualified expert witnesses*’. It is also relevant to note that at para. 23 Finlay Geoghegan J. relied upon the statement of Arnold J. that

“Time after time in the patents court, I see parties agreeing to give disclosure at considerable expense when it turns out it is of no relevance.”

21. She also relied, at para. 32, on the fact that

“Secondary evidence of contemporary events may not be totally excluded in accordance with the decision of the English Court of Appeal in *Molnlycke AV v. Proctor and Gamble Limited (No. 5)* [1994] RPC 49. However, as is clear from that judgment **secondary evidence of that type must be kept firmly in its place** and will vary from case to case.” (Emphasis added)

22. At para. 34, Finlay Geoghegan J. notes that

“Insofar as the claim of lack of sufficiency or plausibility is concerned, it appears to be accepted that such claim falls to be determined by **objective construction of the patent and that again expert evidence will be the only relevant evidence.**” (Emphasis added)

23. *Boehringer* involved revocation proceedings on the grounds of obviousness from prior art, lack of sufficiency and/or plausibility. Four categories were considered by the High Court to be relevant and necessary in relation to the claim seeking to revoke the patent. In the Court of Appeal, it was held that all four categories were relevant and in relation to the first category, the Court of Appeal concluded that the category was relevant and necessary.

24. However, in relation to the other three categories, the Court of Appeal held that although relevant, the categories were not necessary and noted, *inter alia*, that the time period, which was for nine years, would involve significant time and money, that certain of the documents may be subject to privilege and that the parties were major pharma companies with multiple resources available to independently obtain expert scientific and legal advice and so it was not necessary for a fair disposal of the matter for the non-privileged advice and reports, lab notebooks, *etc.* over a nine year period to be discovered. This was against the backdrop of

the court's observations that the primary evidence at the trial is that of properly qualified expert witnesses.

25. It is also relevant to note that leave to appeal the Court of Appeal judgment in *Boehringer* to the Supreme Court was refused by way of a determination of 5<sup>th</sup> May, 2016 [2016] IESCDET 62 and, *inter alia*, the following observations were made by the Supreme Court:

“3. There needs to be **a refocusing** in this case on issues which concern, firstly, the **interpretation of the patent itself and what it teaches** and, secondly, what level of knowledge the team considering the pleaded prior art **would have had as to the state of science at the time of the patent** and whether an inventive step was required in order to arrive at what is alleged by Teva to have been obvious, and therefore not patentable. **Where patent cases are focused in this way, lengthy discovery applications, lengthy submissions and the exchange of vast quantities of documentation become unnecessary.** Furthermore, the issues in the case will be addressed within a **limited timescale by the court of trial** and **expert witnesses will not be called repetitively** on each side.” (Emphasis added)

26. At a time when there is well-publicised pressure on the courts in view of the low number of judges, it is relevant to note that one benefit of more proportional discovery is a saving on court time and this is therefore a situation in which the public interest may well take precedence over litigants' desire for what has become known as the 'perfect truth' or 'perfect justice' – see the comments of Fennelly J, quoted in *Tobin*, at para. 41:

“[A]s Fennelly J. noted in *Ryanair p.l.c. v. Aer Rianta c.p.t.* [2003] 4 I.R. 264, there can be a danger in the over-pursuit of what he described at p. 277 as 'perfect truth'.”

27. This Court adopts the reasoning used by the Supreme Court, *albeit* in the context of a determination not to hear an appeal, to conclude that a further reason for the courts to take a

more focussed approach to discovery not just, but particularly, in patent litigation is that it is likely to lead to a more focused hearing and therefore a saving of court time and an avoidance of the calling of unnecessary witnesses.

**28.** The Supreme Court also observed in dealing with the application for an appeal to that court of the Court of Appeal's judgment in *Boehringer* that:

“11. [...] Another complaint is that what has been set by the Court of Appeal is a ‘a **proportionality test with an unduly low threshold**’ enabling the burden of discovery to be pleaded by an opponent in order to defeat ‘the interests of justice’.” (Emphasis added)

**29.** It is relevant to note that the Supreme Court refused to accept the appeal on the grounds that the proportionality test used in the *Boehringer* patent case was an unduly low threshold. It went on to state:

“12. [...] If, as is clear, the issue is whether an inventive step was taken by the team considering the eventually patented product, **the entire focus of litigation should be on the nature of the prior art** and whether the step or steps leading to what was patented could properly be analysed as being inventive.” (Emphasis added)

**30.** It is clear therefore from both the judgment of the Court of Appeal and the determination by the Supreme Court of the application to appeal that judgment, that there is a clear message being delivered by the appellate courts in patent litigation as to the need for the parties to focus not on obtaining the ‘perfect truth’ but on the evidence of expert witnesses and not on secondary evidence.

**31.** In the High Court case of *Biogen Inc. v. Celltrion Inc* [2018] IEHC 239 Barrett J. relied on the foregoing comments of Finlay Geoghegan J., Arnold J. and the wording of the Determination by the Supreme Court. On this basis, in the case before him, which was an infringement action and a revocation action (as the defendants counterclaimed for invalidity



and sought an order revoking the patents on grounds of added matter, lack of novelty and insufficiency), Barrett J. refused five of the seven categories of discovery sought.

32. Finally, since there is a degree of overlap between the categories sought by the parties from each other in these proceedings, it is relevant to note the comments of Kelly J. (as he then was) in *Medtronic Inc. and Others v. Guidant Corporation and Others* [2007] IEHC 37 at para. 80 that:

“It is difficult to see how the plaintiffs contend that discovery should not be ordered in circumstances where their request for similar documents was obviously considered by them to be both relevant and necessary and was acceded to by the defendants.”

33. Bearing in mind the foregoing, the categories which Novartis seek from Eli Lilly and which Eli Lilly seek from Novartis will be considered in both the revocation action and the infringement action.

#### **(I) ELI LILLY SEEKS DISCOVERY IN REVOCATION ACTION**

34. The validity challenge in the revocation action brought by Eli Lilly against the Patent is broadly that the Patent and/or the scope claimed for it by Novartis:

- seeks to re-monopolise subject matter in the prior art, such that the alleged invention that is the subject matter of the Patent was anticipated by the prior art and lacked novelty as of its priority date; and that,
- in so far as there is any subject matter of the Patent that was not directly anticipated by the prior art, it was obvious over the prior art as of the priority date and/or made no technical contribution to it, so that nothing inventive is disclosed, or obtainable, from the Patent and/or the Patent does not enable a skilled person to perform the claimed invention.

35. It is not disputed that the grounds of challenge are viewed through the eyes of an ordinary person who is skilled in the art and that expert evidence is generally used to, *inter*

*alia*, identify the prior art with precision, to identify the common general knowledge, to identify the person or team with ordinary skill in the art and to identify their attributes, and then to offer opinions to the court on the key issues in dispute.

**36.** There are six categories in dispute in this motion.

**37.** Not unlike the position in *Boehringer*, it is not in dispute that the categories are relevant. Indeed, it is common case that all six categories in this revocation action, which Eli Lilly seeks from Novartis, are also to be found in a very similar form in Categories 3 and 6 which Novartis seeks from Eli Lilly, *albeit* that one should bear in mind that this revocation action (and indeed the infringement action) deal in essence with the validity and extent of a patent owned by Novartis. Therefore the documents in the possession of the *owner* of the Patent, regarding, *inter alia*, antibodies binding to IL-17A/F, IL-17A/A and IL-17A/F/F *etc.* are likely to be of more significance than any such documents in the possession of a party, Eli Lilly, the *challenger* to the Patent and a party that never owned it.

**38.** It is clear from the Particulars of Objection raised by Eli Lilly that the key issue for the trial judge will be what was the state of knowledge and the prior art, as of the priority date.

**39.** With this in mind, the following are the first four categories sought by Eli Lilly.

Category 1:

“All documents which disclose or relate to any tests, studies, trials and/or experiments (including any results, analyses, reports or commentary) concerning whether a murine, humanised and/or human antibody to IL-17A/A binds to and/or neutralises IL-17A/F.”

Proposed time period is from 8<sup>th</sup> July, 2001 to the date of agreement to make this discovery or the Order for discovery.

Category 2:

“All documents which disclose or relate to the identification, generation, analysis and/or function of any antibody (including any fragment thereof) which binds IL-17A/F to the exclusion of binding to other proteins including IL-17A/A and/or IL-17F/F, and/or which preferentially binds IL-17A/F over binding to other proteins including IL-17A/A and/or IL17F/F.”

Proposed time period is 8<sup>th</sup> July, 2001 to the date of agreement to make this discovery or the Order for discovery.

Category 3:

“All documents which disclose or relate to the effect and/or function of any IL-17A/F antibody in respect of the biological activity of IL-17A/F.”

Proposed time period is from 8<sup>th</sup> July, 2001 to the date of agreement to make this discovery or the Order for discovery.

Category 4:

“All documents which disclose or relate to the efficacy of any antibody which binds to and inhibits IL-17A/F to the exclusion of inhibiting IL-17A/A and IL-17F/F in the treatment of any disease.”

**Categories 1-4**

**40.** Novartis is willing to grant Eli Lilly discovery of Categories 1 - 4, subject to a change of the temporal limit.

**41.** Eli Lilly is seeking discovery of all documents from 8<sup>th</sup> July, 2001 to the present, while Novartis is only willing to offer documents two years on either side of the priority date of the Patent, i.e. from the 8<sup>th</sup> July, 2001 to 8<sup>th</sup> July, 2005, which it says is a standard period of discovery in UK patent proceedings.

**42.** Novartis argues that a four-year period for discovery (two years either side in of the priority date of the patent) is generally used as the default or ‘standard disclosure’ in patent proceedings in the UK and a period very close to this temporal period was applied in this jurisdiction in *Boehringer*, where a 4.5 year period was ordered. Novartis claims that the divergence from this four-year-period in the UK is only permitted in exceptional cases.

**43.** Eli Lilly accepts that a four-year period is the default position in the UK but it points out that it is simply that, a default position, and so that in the unusual factual situation in this case, this should not be applied. Eli Lilly points out that, *inter alia*, Novartis had no connection with the Patent during the proposed four year window, as it was owned by Genentech Inc. in the period 2001-2005 and was only acquired by Novartis in 2020. Eli Lilly claims that, *inter alia*, this factor justifies a time span for the discovery of *circa* 20 years rather than a four-year window, particularly when one bears in mind that Novartis actually challenged the Patent when it was in Genentech Inc.’s ownership.

**44.** However, Novartis argues that Eli Lilly has access to these documents in Genentech Inc.’s possession as a result of a US court order to which reference is made below, and therefore this application for discovery is effectively seeking to force Novartis to make discovery of documents that Eli Lilly already has as a result of that court order.

**45.** It is also relevant to note that as regards Genentech Inc.’s ownership of the Patent during the four-year window, uncontroverted submissions were made by Eli Lilly that Novartis has a contractual entitlement to call for documents in the possession of Genentech Inc. relating to this four-year period. For this reason, this Court does not accept that the fact that the patent being challenged was previously owned by a different party is a justification, *per se*, to depart from a period of four years (or indeed four and a half years which was ordered in *Boehringer*).

**46.** In broad terms, the fact that Novartis acquired the Patent many years after its priority date will not impact upon whether the Patent is valid or invalid, which is a key issue in the

case, and so this Court cannot see how, what Eli Lilly has described as an ‘unusual’ fact, should affect the length of discovery to be ordered.

**47.** Similarly, this Court cannot see the significance of the fact that a party that challenged the validity of a patent, when it did not own it, has to the length of discovery to be ordered when it does own it. This is because a key issue, as noted above, in resolving this dispute will be the evidence of expert witnesses around the time of the priority date of the Patent and not the views of challengers, whether Novartis or Eli Lilly, to that Patent many years after the priority date.

**48.** In addition, this Court cannot see anything unusual *per se* in a company first challenging the validity of a patent (presumably because unchallenged, the patent might lead to a restriction on the right of the challenger to market its own product which allegedly fell within the terms of the patent), and then deciding subsequently to acquire the patent, and thereby eliminate the risk of any such litigation.

**49.** In considering whether the default four year period should apply, it is also necessary to refer to a separate argument made by Novartis that Eli Lilly should not be granted the usual discovery since Eli Lilly has already obtained discovery from Genentech Inc., the owner of the Patent during this four year period, pursuant to a US court order.

**50.** The US court order was obtained by Eli Lilly when it obtained a section 1782 Discovery Order for discovery of certain documents from the District Court in the Northern District of California (the “1782 Order”). This order allows for discovery of documents specifically directed at obtaining documents for use in foreign proceedings. Eli Lilly received certain documents under this order, but it says that this does not obviate the need for discovery in this case as the documents sought by Eli Lilly under the 1782 Order were for use generally in its foreign proceedings relating to the IL-17A/F portfolio, and the restrictions that attached to the

1782 Order create practical difficulties in the effective use of those documents obtained under the 1782 Order to assist the disposal of the issues in these proceedings.

**51.** For its part, Novartis claims that, as a result of this 1782 Order, the same documents, that Eli Lilly is now seeking from Novartis, have already been obtained by Eli Lilly and therefore should not be required to be sought from it.

**52.** Eli Lilly emphasises that the restrictions which attach to the 1782 Order make this discovery application necessary. Sworn evidence was provided on behalf of Eli Lilly that these restrictions include the fact the discovered documents cannot be shared with Eli Lilly's EPO counsel who assists in these proceedings, they cannot be shared with experts or external discovery reviewers unless those persons accept they are subject to the jurisdiction of North California District Court and therefore to '*sanction and punishments in the nature of contempt*' from that court in relation to any disclosure of their contents.

**53.** It seems to this Court that this is a legitimate concern on the part of Eli Lilly and, in particular, that it may not be able to source the experts that it wishes because of these restrictions, which restrictions would not be usual in discovery ordered in this jurisdiction.

**54.** For this reason, this Court is of the view that the existence of the 1782 Order is not a sufficient reason for this Court to refuse any of the foregoing categories of documents sought by Eli Lilly.

**55.** This also means that if this Court imposes a time window, it would be doing so on the basis that Eli Lilly is entitled to oblige Novartis to exercise its contractual entitlement to call for documents from Genentech Inc., notwithstanding the existence of the 1782 Order.

**56.** Eli Lilly has described in its written submissions that documents during this four-year widow period relate to:

“the time of most intense development and therefore the window of discovery most likely to capture particularly relevant documents as to, say, obviousness of the alleged invention over material in the known art.”

In this way, these documents will be available to Eli Lilly without restriction, *albeit* that these documents will be available indirectly through Novartis’ contractual entitlement to obtain those documents from Genentech Inc.

**57.** For all the foregoing reasons, including the fact that a very similar period (of four and a half years) was used in *Boehringer*, this Court will grant Categories 1 to 4, notwithstanding the existence of the 1782 Order, but it will not apply a 20 year time period as sought, but will impose a period of four years in relation to those categories.

#### **Category 5**

**58.** The next category for consideration is:

“All documents which disclose or relate to any tests, studies, trials and/or experiments (including any results, analyses, reports or commentary) which concludes that the additional inhibition of IL-17A/F over and above the inhibition of IL-17A/A either does or does not contribute to the efficacy of an anti-IL17-A/A antibody (or any fragment thereof) in the treatment of any disease, including without limitation any documents relating to the trials and experiments referred to in the following publication: *First-in-human study demonstrating the safety and clinical efficacy of novel anti-IL- 17A monoclonal antibody CJM112 in moderate to severe plaque psoriasis, M Kaul et al (2021).*”

**59.** Eli Lilly is seeking the foregoing data relating to a study, known as the *Kaul* publication, which was published by Novartis staff. Eli Lilly claims, and this is uncontroverted by Novartis, that this paper supports Eli Lilly’s case that the patent is invalid, since the paper shows that

additional inhibition of IL-17A/F over IL-17A/A does not confer additional efficacy in the treatment of any disease. Eli Lilly claims that this supports its position, since in reliance on, *inter alia*, this paper, Eli Lilly claims that the subject matter of the invention, which has been patented in this case, makes no technical contribution.

**60.** For its part, Novartis refused to discover this category on the grounds, *inter alia*, that it accepted the data in the publication and so it claims that it is unnecessary to discover this category.

**61.** However, that ignores all the backup documentation and research related to this article in the possession of Novartis, which is clearly highly relevant since it goes to the core of Eli Lilly's claim that the patent is invalid on grounds of making no technical contribution. Furthermore, this is a very specific and strictly defined category of discovery, relating as it does simply to one article and so its discovery could not be said to be disproportionate or lacking a precise category of documents as required by Order 31, Rule 12 (1) of the Rules of the Superior Courts. As it relates to an article which was published in 2021, this Court concludes that a reasonable time period for discovery would be for a period 3 years prior to the publication date of the article.

**Category 6:**

**62.** Category 6 seeks:

“All documents which disclose or relate to any tests, studies, trials and/or experiments (including any results, analyses, reports or commentary) designed and/or carried out in connection with EPO opposition proceedings in respect of EP '084 and/or EP '822 (regardless of whether such tests, studies, trials and/or experiments were used for any other purpose).”



Proposed time period is 3rd February, 2005 to the date of agreement to make this discovery or the Order for discovery.

63. Category 6 is agreed by Novartis, with a start date of 3<sup>rd</sup> February, 2005 on the basis of it listing privileged documents in the ordinary way, on the basis that Eli Lilly would also list their privileged documents in the ordinary way regarding any discovery it provides to Novartis.

64. However, as noted below, this Court has concluded that in relation to the categories of discovery sought from Eli Lilly by Novartis in the revocation action, there is to be no discovery ordered (and so it is not necessary for privileged documents to be listed by Eli Lilly, for the reasons set out below).

65. Accordingly, under this category, Novartis is ordered to list privileged documents in the ordinary way, notwithstanding the reciprocal arrangement does not apply to Eli Lilly.

## **(II) NOVARTIS SEEKS DISCOVERY IN REVOCATION ACTION**

66. The following categories are being sought by Novartis.

### Category 1:

“All documents relevant to, or on which the Petitioner intends to rely on in, the Petitioner’s challenge to the novelty of the subject matter of the Patent, including, but not limited to:

- a. All documents relating to, evidencing or recording the alleged lack of novelty;
- b. All documents concerning the Petitioner’s investigation or assessment of novelty in respect of the state of the art.”

### Category 2:

“All documents relevant to, or on which the Petitioner intends to rely in, the Petitioner’s challenge to the validity of the Patent on the ground of obviousness, including, but not limited to:

- a. All documents relating to, evidencing or recording the alleged obviousness or AgrEvo-obviousness in the light of the state of the art;
- b. All documents concerning the Petitioner’s investigation or assessment of obviousness or AgrEvo-obviousness in the light of the state of the art.”

Category 3:

“All documents concerning, relating to or evidencing any tests, experiments, trials or studies (whether carried out by the Petitioner, or any company in the Eli Lilly group or any third party) which are relevant to the grounds of invalidity set out in the Particulars of Objection and in particular the Petitioner’s novelty, obviousness and AgrEvo-obviousness arguments. For the avoidance of doubt, such documentation includes all documents relevant to any experiments or tests which demonstrate or otherwise whether IL 17A antibodies inevitably, specifically or in any way bind to IL 17 A/F or not and whether or not such documents were prepared for the purposes of these proceedings or otherwise (including but not limited to proceedings before the European Patent Office).”

Category 4:

“All documents relevant to, or on which the Petitioner intends to rely on, in order to demonstrate that the Patent should be revoked on the grounds of insufficiency.”

Category 5:

“All documents containing or referring to any consideration, assessment, or analysis of the ability of the skilled person to perform the invention disclosed in the specification of the Patent.”

Category 6:

“All documents concerning, relating to or evidencing any tests, experiments, trials or studies (whether carried out by the Petitioner, or any company in the Eli Lilly group or any third party) seeking to perform or otherwise put into effect or apply the invention that is the subject of the Patent and/or the specific teaching of the Patent or otherwise relevant to the grounds of invalidity set out in the Particulars of Objection and in particular the Petitioner’s insufficiency arguments.”

Category 7:

“All documents containing or referring to any consideration, assessment, or analysis of whether the claimed features set out in Patent Application WO 2005/010044 are disclosed in the Patent specification as filed.”

Category 8:

“All documents which concern or refer to the issue of the validity of the Patent which have been shown to, provided to, sent to or received from any expert, consultant or in-house counsel and/or patent attorneys who are or had been retained by the Petitioner in respect of such issue.”

**Categories 1, 2 and 4**

67. As a preliminary point, it should be noted that it was clarified by Novartis prior to the hearing that the use of the term ‘or’ ( in the expression ‘*or on which [Eli Lilly] intends to rely*’)

on the first line of the these three categories was not to be read as an alternative, but rather as being in addition to the opening phrase ‘all documents relevant to’.

**68.** In general terms, it is not disputed by Eli Lilly that these categories are relevant. However, it objects to the breadth of the discovery sought. In particular, Eli Lilly claims that many of these categories are very broad e.g. as regards categories 1, 2 and 4, they cover all documents relevant to the challenge to the Patent on the grounds of novelty, obviousness and insufficiency. Eli Lilly claims that this is akin to a defendant seeking all documents from a plaintiff in relation to a claim of negligence by that plaintiff against that defendant. Eli Lilly claims that this category contravenes the terms of Order 31, Rule 12 (1) of the Rules of the Superior Courts which sets down a mandatory requirement for discovery to be sought by reference to ‘*precise categories of documents*’.

**69.** In light of the jurisprudence, to which reference has already been made, this Court sees merit in this argument. Accordingly, while no doubt such a trawl of documents, which, it is to be noted, is unlimited in time, would throw up ‘*relevant*’ documents, it is not ‘*necessary*’ in the sense of it being proportionate, to seek such a broad range of documents from Eli Lilly, which it must be remembered is the challenger to the Patent. As such it is not the party that has developed the Patent or has access to the development materials of the original patentee/Genentech Inc., bearing in mind that the documents sought are ones that relate to the validity of the patent.

**70.** In the circumstances, this Court therefore agrees with the approach of Eli Lilly which is to provide that part of the category that is delimited in some manner, namely the documents upon which Eli Lilly intends to rely, and which therefore are clearly both relevant and necessary. In addition, it seems to this Court that the appropriate time to make this discovery is when Eli Lilly knows for certain what documents it will be relying upon, i.e. upon the delivery of the witness statements.

### **Categories 3, 5, 6, 7 and 8**

71. As regards categories 3, 5, 6, 7 and 8, these are objected to on the grounds that all documentation coming into existence, since 12<sup>th</sup> February, 2017, did so in contemplation of litigation challenging the Patent, such that it is clearly covered by litigation privilege.

### **Documents created in contemplation of litigation?**

72. This claim arises because on the 12<sup>th</sup> February, 2017 Eli Lilly's European patent operations department became aware of the parent of the Patent, i.e. the '822 Patent, as a threat in respect of Eli Lilly's product, *Taltz*.

73. This happened when Eli Lilly became aware that Genentech Inc. applied for supplementary protection certificates in respect of Eli Lilly's own product, *Taltz*, by reference to the '822 Patent in the UK, Italy, France and Spain. In this regard, Eli Lilly made uncontroverted submissions that this amounted to an explicit assertion by Genentech Inc. of the '822 Patent over *Taltz* and so an assertion over *Taltz* of the Patent and so a prelude to an infringement action against Eli Lilly.

74. It seems clear therefore that the 12<sup>th</sup> February, 2017 is the date when Eli Lilly began to review the Patent in contemplation of bringing a challenge to it. Indeed, this conclusion is supported by the fact that within five months of this date, i.e. by 3<sup>rd</sup> July, 2017, Eli Lilly issued proceedings before the High Court of England and Wales seeking revocation of the UK designation of the '822 Patent (which at this time was owned by Genentech Inc.).

75. At this time, Genentech Inc. counterclaimed for infringement in respect of *Taltz*. Eli Lilly also sought a declaration that Genentech Inc.'s application for a supplementary protection certificate in respect of *Taltz* is invalid. In the German courts, Genentech Inc. also asserted the Patent and the German counterpart of the '822 patent over *Taltz*. As there was a European Patent Office opposition to the '822 Patent pending, Eli Lilly intervened in those opposition

proceedings against the '822 Patent and commenced opposition proceedings against the '084 patent.

76. On this basis, it can be seen that there are proceedings in several countries involving Eli Lilly challenging the validity of the Patent, its European patent progenitor and its parent patent, the '822 Patent, all of which is against Novartis or its predecessor in title, Genentech Inc.

77. In this regard, the decision in *Bristol-Myers Squibb Co. v. Merck Sharpe and Dohme Corporation* [2016] IEHC 540 is relevant. This case dealt with an application for discovery where the documents sought were created after the commencement of related US proceedings. At paras. 58 and 59, Costello J. held that:

“In view of the fact that the defendants are seeking this discovery after the date of the initiation of the US proceedings on 4th September, 2014, **it is difficult to conceive of any document which would fall within this category which would not be covered by a claim of privilege.** It is accepted that privilege is not *per se* a valid ground upon which to object to discovery. The plaintiffs object to discovery of this extended category on the grounds of necessity. They say that since privilege will undoubtedly cover material within this category (if any) created since the plaintiffs sued the defendants in the US proceedings, there is nothing to be gained by the defendants by requiring discovery to be made of any such material on the one hand and **such a requirement will merely pose unnecessary costs on the plaintiffs** on the other hand.

I accept this submission. A category of discovery must be necessary for the fair disposal of the cause or matter or for the saving of costs. This category, if ordered, will undoubtedly increase costs and I do not accept that the defendants have established that it is necessary for the fair disposal of the trial. **I do not believe that the listing of**

**documents in the privileged section of an already extensive affidavit of discovery will assist the defendants** in their conduct of the proceedings sufficiently so as to justify the additional expense, which must be incurred if discovery of these documents post 4th September, 2014 is ordered by the Court. On that basis, I hold that the discovery sought is not necessary and I refuse this category of discovery.” (Emphasis added)

**78.** It seems to this Court that the circumstances of this case are very similar to those in the *Bristol-Myers* case, with the initiation of proceedings in this case just five months after the 12<sup>th</sup> February, 2017 (the date when Genentech Inc. applied for supplementary protection certificates in respect *Taltz* and thus a prelude to an infringement action against Eli Lilly).

**79.** Accordingly, as it was in *Bristol-Myers*, it is also not necessary in this case for the fair disposal of the trial that discovery be ordered in respect of documentation, answerable to this category, which was created on or after 12<sup>th</sup> February, 2017. This is because any such documentation would have come into existence in contemplation of this litigation or associated litigation. Similarly, this Court does not believe that the listing of documents in the privileged section of an affidavit of discovery will assist Novartis in its conduct of the proceedings so as to justify the additional time and expense involved in doing same.

### **(III) NOVARTIS SEEKS DISCOVERY IN INFRINGEMENT ACTION**

**80.** The next motion for discovery is brought by Novartis against Eli Lilly in the proceedings in which Novartis claims that Eli Lilly is infringing the Patent. Based on the oral submissions, it appears that the following categories have not been agreed, or fully agreed, and are being sought by Novartis.

#### **Category 1:**

“Such documents as are sufficient to disclose the precise and complete composition of *Taltz* and/or ixekizumab and its binding to and antagonism of IL-17A/F. For the

avoidance of doubt, this category includes all documents relating to any investigation undertaken by the Defendants or any other company in the Eli Lilly group or any third party in connection with Taltz and/or ixekizumab and its binding to and antagonism of IL-17A/F.”

Category 2:

“All documents created at any time evidencing, recording or relating to:

- a. any analysis of EP 2 784 084 (including the Patent) or EP 1 641 822; and
- b. any attempts to determine whether or not Taltz® and/or ixekizumab infringes the Patent or comes within the claims of EP 2 784 084 (including the Patent) or EP 1 641 822.”

Category 3:

“Documents sufficient to disclose the arrangements between the Defendants in respect of the following acts concerning Taltz in the State:

- a) Manufacturing;
- b) Offering for sale;
- c) Putting on the market;
- d) Using;
- e) Importing; or
- f) Stocking.”

Category 4:



“All documents which concern or relate to any consideration and/or decision as to how the Marketing Authorisation for Taltz would be held within the Eli Lilly group and the arrangements whereby any of the Defendants would be entitled to rely on the Marketing Authorisation for Taltz in the carrying out of any aspect of its business.”

Categories 5 and 6:

“All documents containing or evidencing any evaluation or analysis of the relevant product market and/or the identification of competitors, in any of the following:

- a. a therapeutic market for IL-17A inhibitors; and/or
- b. a market for medicines for severe plaque psoriasis where a high degrees of efficacy and speed of therapeutic effect is required, or where there is a need to address the therapeutic failure or decreasing therapeutic effect of first-or second-line biological medicines; and/or
- c. a market for medicines for cases of severe plaque psoriasis affecting joints where speedy therapeutic effect is required; and/or
- d. a market(s) for medicines for the treatment of moderate-to-severe psoriasis; and/or
- e. any other conditions that the Defendants’ product Taltz is authorised to treat,

in the State and/or Europe to include the EEA and the UK and any alleged dominance of the Plaintiff in any of the above.

The above documents should include but not be limited to documents considering, assessing or analysing the following:

(i) product specifications for Taltz, Cosentyx, and/or other products for the treatment of ‘severe psoriasis’ and/or moderate to severe psoriasis and/or any other conditions that Taltz is authorised to treat, including references to efficacy and safety (including comparative efficacy and safety) patients and patient populations, lines of treatment, views of physicians, pricing (including discounts and rebates), [reimbursement], sales and sales forecasts, business and marketing strategies and/or market projections;

(ii) any competitive analysis of Taltz, Cosentyx, and/or other marketed [and pipeline] products, and/or evaluating, assessing, or tracking the sales or prescribing of such products and/or the comparative clinical evaluation of such products; and/or

(iii) patient switching [data] [rates] [to include: (i) patient switching and/or potential switching] from Taltz to Cosentyx and vice versa for each of their therapeutic indications [and/or (ii) patient switching and/or potential switching from Taltz to any other products and vice versa for each of their therapeutic indications.]

Such documents may include, but are not limited to, copies of all internal and/or external communications, surveys, reports, analyses, studies, plans, presentations and comparable documents, whether or not in electronic format, assessing or analysing the relevant product, the substitutability or otherwise of products indicated for the relevant indications, market shares [(including the source and methodology for the calculation of said market shares)], competition, competitors (actual and/or potential), markets, competitive positioning and closeness of competition, international or national prescribing guidelines or statements of medical practice.

Documents that do not relate to at least one of (a) the State (b) the UK or (c) the EEA as a whole, are excluded from the category.

The temporal span for the above request is from 15 January 2015, the date of grant of the marketing authorisation in the EU for Cosentyx.

Regarding sources to be searched for the discovery offered, email accounts and files shared through, stored or saved in Teams or equivalent platforms are included but chat or conference recording on instant messaging platforms such Teams and Skype can be excluded (offered on a reciprocal basis).”

[The sources to be searched for the discovery offered above shall exclude email accounts and electronic messaging platforms (such as Teams or Skype) having regard to the potentially huge volume of emails/electronic messages held by Lilly personnel involved in the marketing of Taltz and the fact that such emails/electronic messages are unlikely to contain anything material falling within these categories that are not otherwise contained in non-email documents sources.]”

### **Categories 1 and 2**

**81.** Eli Lilly says it is a complete answer to these two categories that it has offered a product description, which covers similar ground to the categories sought by Novartis. The product description offered by Eli Lilly is as follows:

“The product description will include the amino acid sequence (i.e. the composition) of ixekizumab and reports detailing experiments conducted in respect of the binding to and antagonism of IL-17A/F and binding to and antagonism of IL-17A/A so as to enable the determination of infringement following the construction of the claims of the Patent.”

In this regard, at paragraph 45 of *Tobin*, Clarke C.J., as he then was, states that:

“The traditional position, very much accepted, **was** that if documents were relevant, their discovery would almost inevitably be necessary. **However, much of the recent case law has indicated a need to move away from that position.** Where there are other equally effectual means of establishing the truth and thus providing for a fair trial then discovery may not be ‘necessary’.” (Emphasis added)

**82.** In light of this principle, it is significant that, Order 94, rule 15 of the Rules of the Superior Courts, even though it was not in force when these proceedings were initiated and so is not directly applicable, provides that in patent proceedings it shall not be necessary for a party to make discovery of documents to the other party relating to the features of a product or process the subject of the litigation, save for special reasons, if full particulars of the product are provided by that party to the other party. This rule states:

“Where a party to proceedings notifies another party of its intention to deliver—

(a) full particulars of the features of the product or process alleged to infringe or breach another party’s rights; and

(b) any necessary drawings or other illustrations,

it shall not be necessary for the notifying party to make discovery of documents relating to the features of the product or process which is the subject matter of the notification, unless the Court, for special reasons to be set out in the Court’s order, otherwise orders.”

**83.** This rule came into effect on 22<sup>nd</sup> October, 2021 which was six months after these proceedings were instituted (on 15<sup>th</sup> April, 2021).

**84.** However, it seems clear that this rule was designed by the Superior Courts Rules Committee to obviate unnecessary discovery in patent litigation and uncontroverted

submissions were made by Eli Lilly in this regard. In these circumstances, it seems to this Court that while Order 94 rule 15 does not *directly* apply to these proceedings, the principle underlying the rule (i.e. a product description, by which is meant full particulars of the product, is in most cases sufficient discovery in patent litigation) means that in this case the product description is, in the words of Clarke C.J., another ‘*means of achieving the same end as that which is sought to be achieved by discovery but at a much reduced cost*’ (at para. 48).

**85.** In this regard, Novartis did not point to any special reasons in this case which would mean that the product description is not sufficient in this case.

**86.** Novartis claims that the fact that Eli Lilly denied the infringement in these proceedings is a special reason for this discovery rule not to apply, because when the Patent was owned by Genentech Inc., Eli Lilly opposed it and related patents, which Novartis says must be because Eli Lilly was concerned that *Taltz* infringed the Patent. However, this Court does not see how the fact that a defendant denies a claim that is made against it (that it is infringing a patent) can be a special reason or in some way exceptional just because it opposed that patent or a related patent on a previous date or just because it was concerned about the extent of a patent or related patents since 2008.

**87.** Indeed, it seems to this Court, what special circumstances exist favour Eli Lilly, namely that any experiments *etc.* which were undertaken by it after 12<sup>th</sup> February, 2017, and so for over five years at the date of this hearing, were in contemplation of litigation and so are likely to be privileged.

**88.** On this basis, this Court concludes that the offer of the product description by Eli Lilly, (which it is to be noted will include reports detailing experiments *etc.* as set out above) is sufficient discovery in this case and accordingly that Categories 1 and 2, in addition thereto, are not therefore necessary.

### **Category 3**

**89.** Eli Lilly says that details of the internal arrangements in Eli Lilly, which are sought in Category 3 by Novartis, relate to highly confidential material, which it would be providing to a direct competitor. It relies on *Tobin* to claim that while it is happy to provide same, it is sufficient that the delivery of these details is postponed until a stage in the proceedings when it is relevant.

**90.** In *Tobin*, at para. 48, Clarke C.J. states:

“[T]he default position should be that a document whose relevance has been established should be considered to be one whose production is necessary. However, that remains **only a default position and one which is capable of being displaced for a range of other reasons.** [...] While not relevant to this case, it might be said that the **postponement of the requirement to disclose confidential documentation may also come into play.**” (Emphasis added)

**91.** It is also relevant to note that in this case, Eli Lilly has admitted in the Defence that the second defendant manufactures ixekizumab, the accused compound, in the State and that the fourth defendant supplies *Taltz*, the accused product in the State. Accordingly, it seems clear that if Novartis is successful in these proceedings that it will be in a position to seek an injunction in respect of Eli Lilly’s manufacture and sale of the alleged offending product and so this Court does not see any prejudice to the delivery of these details being postponed.

**92.** For this reason, this Court accepts that the details should be provided, but that, in light of *Tobin*, it is appropriate to postpone the requirement to disclose this confidential information until it becomes necessary.

#### **Category 4**

**93.** In Category 4, Novartis seeks details of the internal arrangements in the Eli Lilly group regarding the holding of the marketing authorisation for *Taltz*.

**94.** However, the question of who is a market authorisation holder has no implications in a case involving an alleged infringement of a patent, since being a market authorisation holder of a product, which is the subject of a patent, is not one of the prohibited activities, such as manufacturing, stocking, offering for sale *etc.* under s. 40 of the Patents Act, 1992 (as amended). This section states:

“40.—A patent while it is in force shall confer on its proprietor the right to prevent all third parties not having his consent from doing in the State all or any of the things following: (a) making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for those purposes; (b) using a process which is the subject-matter of the patent, or, when the third party knows, or it is obvious to a reasonable person in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in the State; (c) offering, putting on the market, using or importing, or stocking for those purposes, the product obtained directly by a process which is the subject-matter of the patent.”

**95.** This Court has already noted that if Novartis is successful it should be in a position to seek an injunction in respect of Eli Lilly’s manufacture and sale of the alleged offending product (since Eli Lilly has admitted in the Defence that the second defendant manufactures ixekizumab and that the fourth defendant supplies *Taltz* in the State). Accordingly, this Court does not see any prejudice in Novartis not having discovery of details regarding the market authorisation holder and concludes that this category of discovery is not relevant to these proceedings and so this category is refused.

### **Categories 5 and 6**

**96.** Based on the oral submissions of the parties, it seems to this Court that the terms of this category are agreed, subject to the remaining contentious terms in square brackets and each of these will be considered in turn.

**97.** As regards the deletion of reimbursements, these are part of payment for a drug (*albeit* where there is a payment by an individual and the State reimburses the purchase price). For this reason, this Court cannot see how it can be distinguished from other ‘pricing’ which is part of this category.

**98.** Novartis is seeking documents from Eli Lilly detailing any competitive analysis of *Taltz*, *Consentyx* and/or other ‘*marketed and pipeline products*’. Eli Lilly wants this reference to ‘pipeline’ products deleted since it says that this category is concerned with the definition of the market in which the alleged abuse of a dominant position by Novartis is taking place. In this regard, it seems to this Court that products which are not on the market cannot form part of that market definition. Therefore, this Court does not accept Novartis’ claim that products due to come through its pipeline at some future date have a bearing on this alleged dominance. This is because, it is this Court’s view that this case is concerned with claims by Eli Lilly of actual dominance, on the part of Novartis, in the market, not possible or future dominance in the market.

**99.** As regards the deletion of ‘data’ and its replacement with ‘rates’, this Court accepts the point made by Novartis that the term ‘rates’ is a more sterile statistical conclusion, while the term ‘data’ is more likely to include relevant material and so this term should be used, rather than ‘rates’.

**100.** Similarly, this court does not agree to the proposed deletions regarding patient switching proposed by Eli Lilly. This is because patient switching to other products is a crucial issue in defining a product market. In addition, the term ‘for each of their therapeutic



indications' should be added at the end of that paragraph (iii) to ensure consistency with the first part of that paragraph.

**101.** This Court agrees with Novartis that the '*source and methodology for the calculation of [said] market shares*' should not be deleted since this is likely to be relevant to how the market share is calculated.

**102.** Eli Lilly seeks to exclude email accounts from the discovery. However, email is the standard form of communication nowadays and unless there are very good reasons this Court cannot see a basis for excluding email. Eli Lilly has provided sworn evidence of having to search hundreds of gigabytes of material. However, one is dealing here with email which is inherently searchable and also with a large pharma company that would be well used to patent litigation and therefore used to searching for discoverable documents. In the circumstances, this Court will not therefore exclude emails from discovery.

#### **(IV) ELI LILLY SEEKS DISCOVERY IN INFRINGEMENT ACTION**

**103.** The following categories are being sought by Eli Lilly.

##### Category 6:

“All documents from 15 January 2015 which disclose or relate to:

- a) Documents sufficient to show Novartis' market projections for and sales of Cosentyx (secukinumab) from 2015 to present on a country-by-country basis for the EEA (including the UK);
- b) Novartis' business or strategic plans for Cosentyx (secukinumab), including with respect to market shares, competition, competitive positioning and clinical studies / clinical trials / investigator initiated studies; and/or

c) Competitive analyses or assessments of Taltz or any other product(s) that Novartis contends compete with Cosentyx (secukinumab) and/or Taltz (ixekizumab), including relating to each competing product's market share or position, manufacturing, pricing (including rebates and discounting), product specifications, efficacy, sales and marketing, supply chain or distribution.”

Category 7:

“All documents from 24<sup>th</sup> July 2018 which disclose or relate to the purpose for which Novartis acquired the IL-17A/F portfolio, including all documents that disclose or relate to discussions as to the effect of the acquisition of the IL-17A/F portfolio on achieving that purpose.

This category does not encompass documents solely relating to the general commercial objective of Novartis or its wider operations, however it includes such documents where they also disclose or relate to it [*sic*] acquisition and enforcement of the IL-17A/F portfolio.”

Category 8:

“All documents from 1 October 2014 which disclose or relate to any discussion, consideration or assessment of the alleged validity of any of the patents, patent applications or applications for a supplementary protection certificate within the IL-17A/F portfolio.”

Category 9:

“All documents from 25 April 2016 which disclose or relate to any discussion, consideration and/or assessment or whether ixekizumab and/or Taltz fall within the

claims of EP'822, EP'084 and/or the Patent as granted and/or any auxiliary request filed at the EPO and any other patent or patent applications within the IL-17A/F portfolio.”

Category 10:

“All documents [from 15 January 2015] which disclose or relate to any discussion, consideration or assessment of the alleged enforceability of any or all of the IL-17A/F portfolio (including but not limited to the Patent, EP ‘084 and/or EP ‘822 and/or any SPC based on any such patent) against third parties including Lilly or the Lilly Defendants.”

Category 11:

“All documents from 15 January 2015 which disclose or relate to any discussion, consideration and/or assessment of whether Cosentyx and/or secukinumab fall within any of the claims of the Patent [EP ‘084 and/or EP ‘822] [or any of the patents or patent applications within the IL-17A/F portfolio.]”

Category 13:

“All documents which disclose or relate to:

- a. Novartis’ decision to acquire the IL17A/F portfolio from Genentech Inc, and the reasons for said decision;
- b. Novartis’ valuation of the IL17A/F portfolio, including but not limited to the Patent, prior to concluding the transaction that led to its assignment by Genentech Inc, to Novartis;
- c. Novartis’ negotiations with Genentech Inc, for the sale and/or licencing of the IL- 17A/F portfolio, the subsequent divestiture and ultimate assignment of the IL- 17A/F portfolio to Novartis;

d. the consideration paid to Genentech Inc, in connection with Novartis' acquisition of the IL-17A/F portfolio and/or any other financial arrangement arising out of the acquisition of the IL-17A/F portfolio.

Time period: from 24 July 2018 (one year before Novartis AG filed an opposition at the EPO in respect of EP '084)"

Category 14:

"All documents from 24<sup>th</sup> July 2018 which disclose or relate to any discussion, consideration or assessment of:

b) any efforts by Novartis to license the IL 17-A/F portfolio following Novartis' purported acquisition of the IL17- A/F portfolio; and/or"

Category 16:

"All documents from 15 January 2015 which disclose or relate to:

a) non-response or poor response of patients to Cosentyx in respect of each of the therapeutic indications for Cosentyx."

Category 17:

"All documents which disclose Novartis' enforcement strategy for the IL-17A/F portfolio, including the Patent, and any other national designations of EP '084 and any application for any Supplementary Patent Certificate related to Taltz (ixekizumab) based on the Patent and/or any other national designations of EP '084;

This category does not include documents which implement the enforcement strategy in litigation proceedings either in final or draft form."

Time period from 24<sup>th</sup> July, 2018.

### **Background to these categories**

**104.** In Eli Lilly's Defence to the infringement proceedings it claims that the acquisition by Novartis of the Patent '*and/or the IL- 17 A/F portfolio and the bringing of the infringement proceedings constitutes an abuse of*' Novartis' dominant position in the State in the market for medicines for psoriasis.

**105.** Eli Lilly points out that as regards the IL-17A/F portfolio, the original patent which was asserted was Patent '822, that subsequently was rendered invalid in Europe. After that, out of that portfolio came the Patent which is being asserted in these proceedings and Novartis has made an application for a supplementary protection certificate ("SPC") on the basis of the Patent which would extend its range. Eli Lilly claims that it is concerned that there are more divisional patents of Patent '822 which may be asserted in the future against *Taltz*. On this basis Eli Lilly claims that the acquisition of the IL-17A/F portfolio has competition law implications and this is why discovery should be given in respect of the portfolio, rather than the Patent.

**106.** When asked to particularise the 'relevant markets' for the purposes of these proceedings, Eli Lilly referenced its Defence, which claims that Novartis is 'dominant in the State', and it is this dominance in the State which it has 'abused'.

**107.** It is also relevant to note that in Novartis' Reply and Defence to Counterclaim, it claims that as of yet no SPC has been granted and so there is no basis for there being any adjudication upon the validity of a SPC.

**108.** It seems to this Court that these proceedings are about one patent, i.e. Patent '084 and not Patent '822 which is invalid or a SPC that does not exist. Similarly, it is important to note that the invalidity action is not a claim that a portfolio is invalid, but rather that the Patent is invalid, and the infringement action is not a claim that *Taltz* infringes a portfolio, but rather that it infringes the Patent. With this in mind, the categories will be considered.

## **Category 6**

**109.** This Court concludes that, as the claim relates to abuse of dominance in the State and as Eli Lilly is seeking documents in a similar category from Novartis on the basis of the EEA as a whole, sub-category (a) should read '*from 2015 to present for Ireland, the EEA as a whole and the United Kingdom*' instead of the current wording.

**110.** This Court agrees with Novartis' suggestion that the plans be limited to final plans rather than the drafts or rewrites of plans. Hence the term 'final version of' should be inserted on the first line of sub-category (b) before the word 'business'.

**111.** Since sub-category (b) is directed at the product market and the abuse of a dominant position, this Court agrees with Novartis that clinical trials and clinical studies should be excluded from the second paragraph of the category.

## **Category 7**

**112.** This Court understands from the submissions made by the parties that this category has been agreed.

## **Categories 8-11**

**113.** These categories are plainly relevant since they deal with issues such as whether *Taltz* falls within the claims of the Patent and their relevance is implicitly recognised by Novartis in its oral submissions, when it suggested that it would provide these documents to Eli Lilly if Eli Lilly provided documents under Category 2 of Novartis' discovery against Eli Lilly in the infringement action.

**114.** However, in this regard the positions of Eli Lilly and Novartis are different, since Novartis is the owner of the Patent and Eli Lilly is the owner of the product which allegedly infringes the Patent. This difference in their respective positions is recognised by Order 94, rule 15, to which reference has already been made, regarding discovery by the *owner* of a

product which allegedly infringes a patent (*albeit* that this rule only came into force after the institution of the proceedings in this case). However, all this rule does is recognise a difference that has always existed, between the respective positions of a patent owner and the owner of the allegedly infringing product, when it comes to discovery.

**115.** For these reasons, this Court concludes that this is an instance where reciprocity is not the correct basis for ordering discovery.

**116.** As these categories are relevant, Categories 8 to 11 will be ordered. In relation to Category 10, this category deals with the alleged enforceability of the IL-17A/F portfolio against third parties and so the appropriate time period is from the 15<sup>th</sup> January, 2015, since this is the date when Novartis was granted a marketing authorisation for *Cosentyx*. In relation to the two options in square brackets in Category 11, this Court concludes that the reference should be to ‘*the Patent EP ‘084 and/or EP’ 822*’, as suggested by Novartis, since as observed above, this litigation is not relating to a claim that *Taltz* infringes the portfolio and is therefore invalid, but rather that it infringes the Patent.

### **Category 13**

**117.** Based on the oral submissions, there appears to be agreement between the parties regarding Category 13, subject to there being a confidentiality club which should not be an issue in proceedings of this nature and indeed Eli Lilly has confirmed that it has no issue with same.

### **Category 14(b)**

**118.** This Court sees merit in Eli Lilly’s argument that licensing of the IL-17A/F portfolio to parties other than Eli Lilly could be relevant to the abuse of dominant position claim, for example if it showed discriminatory behaviour on the part of Novartis.

**119.** In the circumstances, this Court will order this category but it acknowledges Novartis' point that when it comes to inspection and production, as distinct from listing documents as part of discovery, that the issue of confidentiality may have to be considered at that stage.

**Category 16**

**120.** This Court accepts Eli Lilly's claim that documents which might indicate the poor performance of *Cosentyx* (in contrast to what Eli Lilly claims is *Taltz's* superior performance) are relevant and necessary to Novartis' alleged motivation for seeking to abuse its alleged dominant position. Accordingly, this category will be ordered.

**Category 17**

**121.** This category is agreed between the parties.

**CONCLUSION**

**122.** For the foregoing reasons, this Court will order discovery of the categories of documents in line with this judgment.

**123.** This Court orders the parties to engage with each other to see if agreement can be reached regarding all outstanding matters without the need for further court time, with the terms of any agreed draft court order to be provided to the Registrar. In addition, as there were numerous versions of the categories and some correspondence between the parties while the hearing was ongoing, it is possible that the form of one or two categories relied upon by this Court may have been superseded by this interaction, in which case, and in the absence of agreement between the parties, this matter can be dealt with before final orders are issued.

**124.** If it is necessary for this Court to deal with final orders, this case will be provisionally put in for mention one week from the date of delivery of this judgment, at 10.45 am (with liberty to the parties to notify the Registrar, in the event of such listing being unnecessary).